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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,130	11/18/2003	Matthias Straub	029300.51815US	1917

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,130	STRAUB ET AL.	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7 and 16-38* is/are rejected.

7)☒ Claim(s) *4 and 8-15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *April 13, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-38 ARE PRESENTED FOR EXAMINATION

Applicants' Information Disclosure Statement filed April 13, 2004 has been received and entered into the application. Accordingly, as reflected by the attached, completed copy of form PTO/SB/08a (1 page), the cited references have been considered.

Specification/Claim Objection

The specification and claims 1, 5 and 11 are objected to because of the following informality:

Throughout the specification and the above claims the term "anti-arrhythmic" is improperly employed. That is, in claim 1, for example, it is set forth that the therapeutic objective is one of "treating or inhibiting ***anti***-arrhythmic events"(emphasis added). However, such would mean that the objective would be to promote an arrhythmic event, which is clearly not what is intended. Appropriate correction of both the specification and claims is required.

Claims 4 and 8-15 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance. None of the references teach or would have fairly suggested the presently claimed, specific dosing regimen.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-7 and 16-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoen et al. (U.S. Patent No. 4,550,112 "Schoen '112"), Schoen et al. (U.S. Patent No. 4,912,113 "Schoen '113") in view of Schoen et al. (U.S. Patent No. 5,324,732 "Schoen '732").

Schoen '112 and '113 teach a method of treating arrhythmias which comprises the administration of 3,7-diazabicyclo(3.3.1)nonane compounds of the type claimed to a human in need thereof (see Schoen '112 at col. 5, lines 6-68 and col. 11, lines 7-25 and Schoen '113 at col. 1, line 26 - col. 2, line 26 and col. 12, line 61 – col. 13, line 14, line 28). The administration may be orally (claim 1 encompasses oral administration) or parenterally and liquid dosage forms are taught therefor (Schoen '112 at col. 14, lines 17-37 and Schoen '113 at col. 14, lines 29-48).

The differences between the above and the claimed subject matter lay in that the primary references fail to highlight:

(1) the claimed dosage regimen;

(2) the claimed fumaric salt (e.g., claim 21);

(3) the specific types of arrhythmias (claim 5); and

(4) the claimed packaged product (claims 25-38).

However, to the skilled artisan, the claimed subject matter would have been obvious because:

(1) The administration of divided oral dosages or multiple bolus infusions (i.e., "plurality of successive phases" of claim 1) of medicaments were well known modes of administering active agents for the treatment of various disease states. Such modes could be considered "non-continuous" (claim 2) or "partially continuous" (claim 3) depending on the length of time such administration is needed for the treatment of the disease and how often treatment is required, i.e., for the arrhythmia in the case of the teachings of the primary references. Given that both primary references teach oral or parenteral administration in general, it would have been appreciated by the skilled artisan that such uncomplicated modes of administration were well within the teachings of the references.

2) Schoen '112 at col. 6, line 14 and Schoen '113 at col. 7, line 7 specifically teach that fumaric acid salts may be employed while Schoen '732 teaches that the specifically claimed fumaric salt was known to be a pharmaceutically acceptable salt (col. 2, lines14-32).

(3) As noted above, Schoen '112 and Schoen '113 teach the treatment of arrhythmias in general and thus would have encompassed the specific arrhythmias claimed.

(4) In the pharmaceutical art it is required that a pharmaceutical manufacturer include a package insert, i.e., instruction/labeling means, containing instructions for the use of the packaged pharmaceutical when delivered to a pharmacy or else placed in commerce. The specific printed information is not material covered under patent laws, but rather copyright laws. Also, even if such were covered under patent laws, the limitation in the claim relating to the subject matter of the printed matter is seen as no more than a statement of intended use for the

claimed composition and such a statement does not impart any physical limitation to the composition that is not found in, or made obvious by the references relied upon.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims1-3, 5-7 and 16-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/894,364.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the administration of divided oral dosages or multiple bolus infusions (i.e., "plurality of successive phases" of claim 1) of medicaments were well known modes of administering active agents for the treatment of various disease states. Such modes could be considered "non-continuous" (claim 2) or "partially continuous" (claim 3) depending on the length of time such administration is needed for the treatment of the disease and how often treatment is required, i.e., for the arrhythmia in the case of the co-pending claims. Given that the co-pending claims are directed to "administering" in general, it would have been appreciated by

the skilled artisan that such uncomplicated modes of administration were well within the scope of the co-pending claims.

Also, while host of the co-pending claims is limited to a male human patient, such is not seen to provide a patentable distinction because in the present claims the host may be "a human" in general and thus would include a human male.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

None of the claims are allowed.

The references cited by the Examiner on the attached form PTO-892 and not relied upon are included to show the general state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

September 28, 2004